

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE et al.

Appl. No. 09/350,401

Filed: July 8, 1999

For: Inducing Cellular

Immune Responses to Hepatitis B Virus Using Peptide and Nucleic Acid

**Compositions** 

Confirmation No. 8008

Art Unit: 1644

Examiner: Schwadron, R.

Atty. Docket: 2060.0060008/EKS/PAJ/M-M

First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental IDS is a continuation of the numbering in Applicants' Information Disclosure Statement filed electronically herewith in connection with the above-captioned application. Copies of documents AL2, AM2, AO2, AS1, AR5, AR20 and AS21 were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/239,043, filed January 27, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120 and submitted as document AT42 as cited on the Second Supplemental IDS filed herewith. Thus, copies of the above-listed documents are not attached. 37 C.F.R. § 1.98(d). Copies of all other documents are attached.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AM1, AP1, and AN2 cited on Form PTO 1449:

Document AM1, European Application No. EP 0 226 513 A1, is in the French language. An unverified English language abstract of document AM1 is attached as document AS25.

Document AP1, PCT International Publication No. WO 92/21033, is in the German language. An unverified English language abstract of document AP1 is attached as document AT25.

Document AN2, PCT International Publication No. WO 94/11738, is in the German language. An unverified English language abstract of document AN2 is attached as document AR26.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

SETTE *et al*. Appl. No. 09/350,401

- 3 -

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits. No fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Peter A. Jackman Attorney for Applicants

Registration No. 45,986

Date: August 5,2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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	ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M	APPLICATION NO. 09/350,401				
APPLICANT SETTE et al.						
	FILING DATE July 8, 1999	GROUP 1644				

# FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

				<b>v.s.</b>	PATENT DOCUMENTS			
EXAMINER INITIAL		DOCUMENT NUMBER		DATE	NAME	CLASS	SUB- CLASS	FILING DATE
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EXAMINER INITIAL		DOCUI	MENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0	044 710 A1	01/27/1982	Europe			Yes No
	AM1	EP 0	226 513 A1	06/24/1987	Europe			Yes X No
	AN1	WO 92	2/02543 A1	02/20/1992	WIPO			Yes No
	A01	WO 92	2/12996 A2	08/06/1992	WIPO			Yes No
	AP1	WO 92	2/21033 A1	11/26/1992	WIPO			Yes X No
			OTHER (Inclu	ding Author,	Title, Date, Pertinent Pag	es, etc.)		
	Aichele, P., et al., "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide," J. Exp. Med. 171:1815-1820, Rockefeller University Press (1990)						in vivo Rockefeller	
	AS	1	Alexander, J., et al., "Derivation of HLA-All/K <sup>b</sup> Transgenic Mice. Functional CTI Repertoire and Recognition of Human All-Restricted CTL Epitopes," <i>J. Immunol</i> . 159:4753-4761, The American Association of Immunologists (1997)					ctional CTL Immunol.
	Bergmann, C.C., et al., "Differential Effects of Flanking Residues on Presentation of Epitopes from Chimeric Peptides," J. Virol. 68:5306-5310, American Society for Microbiology (August 1994)							
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	AL2	WO 93	3/03764 A1	03/04/1993	WIPO				Yes No
	AM2	WO 94	1/03205 A1	02/17/1994	WIPO				Yes No
	AN2	WO 94	1/11738 A1	05/26/1994	WIPO				Yes X No
	AO2	WO 94	1/20127 A1	09/15/1994	WIPO				Yes No
	AP2	WO 96	5/03140 A1	02/08/1996	WIPO				Yes No
			OTHER (Incl	uding Author,	Title, Date, Pertine	nt Pages,	etc.)		
	AR	<u>2</u>	Supermotif Patients w	s Predict Bro with Acute Hep	Tuman Histocompatibile adly Cross-reactive (atitis," <i>J. Clin. In</i> avestigation, Inc. (19	Cytotoxic vest. 100:	T Lymp	hocyte Re	sponses in
	Bertoni, R., et al., "Human Class I Supertypes and CTL Repertoires Extend to Chimpanzees," J. Immunol. 161:4447-4455, American Association of Immunologists (1998)								
	АТ	<u>2</u>			"Structure of the hure 329:506-512, Macmil				
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Confirmation No. 8008

Art Unit: 1

Examiner: Schwadron, R.

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### **Second Supplemental Information Disclosure Statement**

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Sir:

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AT42. Thus, copies of the above-listed documents are not attached. 37 C.F.R. § 1.98(d). A copy of all other documents is attached.

The Examiner's attention is directed to the following co-pending U.S. patent applications:

- U.S. Application No. 08/591,502, filed May 20, 1996;
- U.S. Application No. 09/350,401, filed July 8, 1999;
- U.S. Application No. 09/239,043, filed January 27, 1999; and
- U.S. Application No. 10/363,990, filed March 10, 2003;

which are directed to related technical subject matter. The identification of these U.S. patent applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Peter A. Jackman Attorney for Applicants Registration No. 45,986

Date: August 5, 2003

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ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M	09/350,401		
APPLICANT SETTE et al.			
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	AL3	EP (	0 429 816 A1	06/05/1991	Europe			No
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	AN3	EP (	491 077 A1	06/24/1992	Europe			Ye:
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	AO3	WO S	93/03753	03/04/1993	WIPO		-	No
	AP3	WO 9	94/19011	09/01/1994	WIPO			Yes
	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR							
	AS	26	Alexander, J in Vaccine D	., et al., "? evelopment,"	The Optimization of Immunol. Res. 18:7	Helper T Ly 9-92, Humana	ymphocyte (H' a Press Inc.	TL) Function (1998).
	AT	26	Transgenic M	ouse Model of	nisms of Class I Re f Fulminant Hepatit cess (November 1993	is," <i>J. Exp</i>		
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M	APPLICATION NO. 09/350,401			
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	AL4	WO 9	5/03777	02/09/1995	WIPO			Ye N		
	AM4	WO 9	95/22317	08/24/1995	WIPO			Ye N		
	AN4	WO 9	9/45954	09/16/1999	WIPO			Ye ~N		
	A04	EP 1	018 558 A2	07/12/2000	Europe			Ye: No		
	AP4	WO 0	2/19986 A1	03/14/2002	WIPO			Ye. N		
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	Barnaba, V., et al., "Selective killing of hepatitis B envelope antigen- specific B cells by class I-restricted, exogenous antigen-specific T lymphocytes," Nature 345:258-260, Nature Publishing Co. (1990).									
	Bertoletti, A., et al., "Definition of a Minimal Optimal Cytotoxic T-Cell Epitope within the Hepatitis B Virus Nucleocapsid Protein," J. Virol. 67:2376-2380, American Society for Microbiology (April 1993).									
Bertoletti, A., et al., "Natural variants of cytotoxic epitopes are T-cell receptor antagonists for antiviral cytotoxic T cells," Nature 369:407-410, Nature Publishing Co. (June 1994).										
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<u>SECOND SUPPLEMENTAL</u> INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M	APPLICATION NO. 09/350,401
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	AR	<u>28</u>	recognize end	Bertoletti, A., et al., "HLA class I-restricted human cytotoxic T cells recognize endogenously synthesized hepatitis B virus nucleocapsid antigen,"  Proc. Natl. Acad. Sci. USA 88:10445-10449, National Academy of Sciences (1991)				antigen,"
	AS	<u>28</u>	Bertoni, R., et al., "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis," J. Clin. Invest. 100:503-513, The American Society for Clinical Investigation, Inc. (1997).					
	АТ	28	Bhatnagar, P.K., et al., "Immune response to synthetic peptide analogues of hepatitis B surface antigen specific for the a determinant," Proc. Natl. Acad. Sci. USA 79:4400-4404, National Academy of Sciences (1982).					
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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	AR	<u>29</u>	Borras-Cuesta	a, F., et al. determinants	, "Engineering of immunds recognized by B and T o	ogenic p	peptides by		
	Bruss, V., "A Short Linear Sequence in the Pre-S Domain of the Large Hepatiti AS 29 B Virus Envelope Protein Required for Virion Formation," J. Virol. 71:9350-9357, American Society for Microbiology (1997).							je Hepatitis 71:9350-	
	AT	<u>29</u>	Celis, E., et Lymphocytes," Immunologists	$^{\prime}$ J. Immunol.	nition of Hepatitis B Su 140:1808-1815, The Amer	ırface l	Antigen by H ssociation c	luman T of	
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	AS	30	Chisari, F.V., "Hepatitis B Virus Immunopathogenesis," <i>Annu. Rev. Immunol.</i> 13:29-60, Annual Reviews Inc. (1995).									
	AT	30	Alleles Allo	ws Definition	1., "Binding of a Pept: n of an A2-Like Superty of Immunologists (199	уре," <i>J</i> .	en to Multij Immunol. 15	ole HLA 4:685-693,				
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	AR	<u>31</u>	Nonstructural	Protein 3 i	"Immunodominant CD4* T-C n Acute Hepatitis C Virt ciety for Microbiology	ıs Infe	tope within ction," J. V	irol.		
	AS	31	Synthetic Pep	Fayolle, C., et al., "In Vivo Induction of Cytotoxic T Cell Response by a Free Synthetic Peptide Requires $CD4^*$ T Cell Help," J. Immunol. 147:4069-4073, The American Association of Immunologists (1991).						
	AT	31	Hepatitis B V	irus Nucleoc	ntification of Immunodon apsid Antigen," <i>J. Clin.</i> ical Investigation, Inc.	(1991)	. 88:214-22	pes of the 2, The		
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	AR	<u>32</u>	Antigen (Hbs/	g) and Their	nesis of Peptide Fragmen: Immunogenicity," in Pe undation, Osaka, Japan, j	ptide C	hemistry, Mu	ınekata, E.,			
	AS	Hayashi, Y., et al., "Studies on Peptides. CLXVI. Solid-Phase Syntheses and Immunological Properties of Fragment Peptides Related to Human Hepatitis B Virus Surface Antigen (HbsAg) and Its Pre-S2 Gene," Chem. Pharm. Bull. 36:4993-4999, Pharmaceutical Society of Japan (1988).									
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	AR	33	Lymphocytes	Generated by	Class I MHC-restricted, Peptide Priming In Viv G Harbor Laboratory Pre	o, " in V	accines 90,	Brown, F.,				
	AS	33	Binding to H	ondo, A., et al., "Prominent Roles of Secondary Anchor Residues in Peptide inding to HLA-A24 Human Class I Molecules," <i>J. Immunol. 155</i> :4307-4312, The merican Association of Immunologists (1995).								
	AT	33	Immunogenic	for CD4 T Ce	onserved Hepatitis C Vi lls: Implications for S ssociation for the Stud	Vaccine	Development,	" Hepatology				
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<u>SECOND SUPPLEMENTAL</u>

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next communication to Applicant.

ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M APPLICATION NO. 09/350,401

APPLICANT

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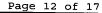




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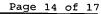
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	AS	<u>40</u>	Cytotoxic T C	Sattegay, M., et al., "Patients with Chronic Hepatitis C Have Circulating Sytotoxic T Cells Which Recognize Hepatitis C Virus-Encoded Peptides Binding to LLA-A2.1 Molecules," <i>J. Virol.</i> 69:2462-2470, American Society for Microbiology 1995).					
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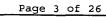




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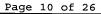
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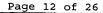
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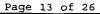
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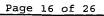
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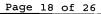
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FORM PTO-1449

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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1	APPLICANT SETTE et al.	
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	Reddehase, M.J., et al., "A pentapeptide as minimal antigenic determinant for MHC class I-restricted T lymphocytes," Nature 337:651-653, Macmillan Publishers, Ltd. (1989)							
	AS	17	Romero, P., et al., "H-2K <sup>d</sup> -restricted Antigenic Peptides Share a Simple Binding Motif," <i>J. Exp. Med.</i> 174:603-612, Rockefeller University Press (1991)					
	AT	17	Rothbard, Opin. Imm	J.B., "Major unol. 2:99-10	histocompatibility comple 5, Current Biology, Ltd. (	x-peptide i 1989)	interaction	ns," Curr.
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	AS	<u>18</u>	Histocompa	schke, O., et al., "Characterization of Naturally Occurring Minor occupatibility Peptides Including H-4 and H-Y," <i>Science 249</i> :283-287, American ciation for the Advancement of Science (1990)						
	AT	<u>18</u>	Rötzschke, O., and Falk, K., "Naturally-occurring peptide antigens derived from the MHC class-I-restricted processing pathway," <i>Immunol. Today 12</i> :447-455, Elsevier Science Publishers, Ltd. (1991)					rived from -455,		
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## FIRST SUPPLEMENTAL

	APPLICATION NO. 09/350,401
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INFORMATION DISCLOSURE STATEMENT FILING DATE GROUP July 8, 1999 1644 U.S. PATENT DOCUMENTS EXAMINER DOCUMENT DATE INITIAL NAME CLASS SUB-FILING DATE NUMBER CLASS AΑ AΒ AC ΑD ΑE AF AG AΗ ΑI АJ AK FOREIGN PATENT DOCUMENTS EXAMINER INITIAL DOCUMENT DATE COUNTRY CLASS SUB-TRANSLATION NUMBER CLASS Yes ALNo Yes AM No Yes AN No Yes AΟ No Yes ΑP No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Rotzschke, O., et al., "Peptide motifs of closely related HLA class I molecules encompass substantial differences," Eur. J. Immunol. 22:2453-2456, VCH AR <u> 19</u> Verlagsgesellschaft mbH (September 1992) Rötzschke, O., and Falk, K., "Origin, structure and motifs of naturally processed MHC class II ligands," *Curr. Opin. Immunol.* 6:45-51, Current Biology, Ltd. AS <u> 19</u> (February 1994) Rudinger, J., "Characteristics of the amino acids as components of a peptide ΑT <u>19</u> hormone sequence," in Peptide Hormones, Parsons, J.A., ed., University Park Press, Baltimore, MD, pp.1-7 (1976) EXAMINER DATE CONSIDERED

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FIRST SUPPLEMENTAL

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APPLICANT SETTE et al.	

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	AR	20	Ruppert, a	Ruppert, J., et al., "Prominent Role of Secondary Anchor Residues in Peptide Binding to HLA-A2.1 Molecules," <i>Cell</i> 74:929-937, Cell Press (September 1993)					
	AS	20	recognition	Schulz, M., et al., "Major histocompatibility complex binding and T cell recognition of a viral nonapeptide containing a minimal tetrapeptide," Eur. J. Immunol. 21:1181-1185, VCH Verlagsgesellschaft mbH (1991)					
	Sette, A., et al., "Prediction of major histocompatibility complex binding regions of protein antigens by sequence pattern analysis," Proc. Natl. Acad. Sci. USA 86:3296-3300, National Academy Press (1989)						inding 1. Acad. Sci.		
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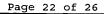
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	AS	21	Immunogen:	Sette, A., et al., "The Relationship Between Class I Binding Affinity and Immunogenicity of Potential Cytotoxic T Cell Epitopes," <i>J. Immunol. 153</i> :5586-5592, The American Association of Immunologists (December 1994)					
	AT	21	Shastri, N., et al., "Presentation of Endogenous Peptide/MHC Class I Complexes Is Profoundly Influenced by Specific C-Terminal Flanking Residues," <i>J. Immunol.</i> 155: 4339-4346, The American Association of Immunologists (1995)						
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	AS	<u>22</u>	Shimojo, N J. Immunoj	Shimojo, N., et al., "Specificity of peptide binding by the HLA-A2.1 molecule," . Immunol. 143:2939-2947, The American Association of Immunologists (1989)					
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	AS	23	cytotoxic	Wentworth, P.A., et al., "Differences and similarities in the A2.1-restricted cytotoxic T cell repertoire in humans and human leukocyte antigen-transgenic nice," Eur. J. Immunol. 26:97-101,VCH Verlagsgesellschaft mbH (1996)					
	AT	23	Lymphocyte	Atton, J.L., et al., "Molecular Analyses of a Five-Amino-Acid Cytotoxic T- mphocyte (CTL) Epitope: an Immunodominant Region Which Induces Nonreciprocal L Cross-Reactivity," J. Virol. 63:4303-4310, American Society for Microbiology 289)					

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	AT	<u>24</u>	viral and		n HLA-All-specific motif in eins," <i>Proc. Natl. Acad. S.</i> 93)					
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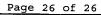
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